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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/532,432

10/03/2006

Gregory D. Plowman

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04/02/2010

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

04/02/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/532,432 | <b>Applicant(s)</b><br>PLOWMAN ET AL. |  |
|                              | <b>Examiner</b><br>Karen A. Canella  | <b>Art Unit</b><br>1643               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 15, 16, 18, 20-22, 24, 25, 31, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 18, 20-22, 24, 25 and 35 is/are allowed.
- 6) ☒ Claim(s) 15, 31 and 34 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

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### **DETAILED ACTION**

Claims 8-13, 17, 19, 26-30 have been canceled. Claims 1, 2, 4, 5, 18, 20 and 31 have been amended. Claims 1-7, 15, 16, 18, 20-22, 24, 25, 31, 34 and 35 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 31 has been amended to require the use of a tissue-matched control. This embodiment is not supported by the originally filed disclosure which does not describe a tissue matched control sample contacted with a probe for MAP2K6 expression.

Claims 15 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse expressing MP2K6, does not reasonably provide enablement for a transgenic non-human animal expressing MAP2K6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is recognized in the art, that although the technology developed to generate transgenic mice is becoming predictable and reliable, the application of this technology to other animals is

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difficult and unreliable. The abstract of Charreau et al (Transgene Research, 1996, Vol. 5, pp. 223-234, cited in the previous Office action) teaches that although the procedure of microinjection into fertilized rat ova is an established procedure, transgenic rats remain difficult to produce in comparison with mice, and that fewer than 20 transgenic rat lines have become established by 1996. The abstract of Nancarrow et al (Methods in molecular biology, 1993, vol. 18, pp. 273-303, cited in a previous Office action) acknowledges that the production of transgenic sheep has proved to be very difficult compared to the production of transgenic mice. The abstract of Machaty et al (Cloning Stem Cells, 2002, Vol. 4, pp. 21-27, cited in a previous Office action) published the year after the filing date of the instant application, states that although genetic manipulation of mice has been possible for over two decades, the technology of nuclear transfer and homologous recombination has not been effective for the production of transgenic pigs.

The specification does not teach the particulars of making a transgene construct wherein introduction of said transgene construct into a non-human animal produces a transgenic non-human animal, thus, the teachings of the art at the time the specification was filed must be relied upon for enablement. For the reasons set forth above, the art acknowledges that the application of the technology of making transgenic mice to the making of other non-human mammals is unreliable and unsuccessful, one of skill in the art would be subject to undue experimentation in order to make the broadly claimed transgenic animals and use them in the claimed methods.

Claims 15, 31 and 34 are rejected.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims

Claims 1-7, 18, 20-22, 24, 25 and 35 are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828.

The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/  
Primary Examiner, Art Unit 1643